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Sally Yeager
Alcon Research Ltd.
R&D Counsel Q-148
6201 South Freeway
Fort Worth, TX 76134-2099

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,911,920

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,911,920, which claims the human drug product Betaxon (levobetaxolol) and a method of its use, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 565 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 565 days (1.5 years).

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 26, 2002 (67 Fed. Reg. 43128). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2}(\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2}(765 \text{ days}) + 182 \text{ days} \\ &= 565 \text{ days (1.5 years)}\end{aligned}$$

Since the regulatory review period began July 23, 1997, after the patent issue date (March 27, 1990), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,911,920
Granted:	March 27, 1990
Original Expiration Date ¹ :	March 27, 2007
Applicant:	Rajni Jani et al.
Owner of Record:	Alcon Manufacturing, Ltd.
Title:	Sustained Release, Comfort Formulation for

¹Subject to the provisions of 35 U.S.C. § 41(b).

Glaucoma Therapy

Product Trade Name: Betaxon (levobetaxolol)

Term Extended: 565 days

Expiration Date of Extension: October 12, 2008

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.

Kery Fries
Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

RE: Betaxon (levobetaxolol)
FDA Docket No.: 00E-1402

Attention: Claudia Grillo